> +

Approved for use through 10/31/2002. OMB 0651-0031 U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

Complete if Known

SUBSTITUTE TO THE STATE OF THE STATEMENT BY APPLICANT (use as many sheets as necessary)

of 6

Complete if Known					
Application Number	10/647,119				
Filing Date	August 25, 2003				
First Named Inventor	Michael R. VIOLANTE et al.				
Group Art Unit	3737				
Examiner Name	Unassigned				
Attorney Docket Number	32286-192289				

U.S. PATENT DOCUMENTS						
Examiner Initial	Document Number	Date	Name	Class	Sub- Class	Filir Dat
/WI	3,695,921	10/3/72	SHEPHERD, et al.			
7	4,100,309	7/11/78	MICKLUS, et al.			
	4,345,602	8/24/82	YOSHIMURA, et al.			
	4,373,009	2/8/83	WINN			
	4,401,124	8/30/83	GUESS, et al.			
	4,456,017	6/26/84	MILES			
	4,459,317	7/10/84	LAMBERT			
	4,585,666	4/29/86	LAMBERT			
1	4,589,873	5/20/86	SCHWARTZ			
	4,642,267	2/10/87	CREASY, et al.			
	4,682,607	7/28/87	VAILLANCOURT			
	4,721,117	1/26/88	MAR, et al.			
	4,729,914	3/8/88	KLIMENT, et al.			
	4,739,768	4/26/88	ENGELSON		*	
	4,769,013	9/6/88	LORENZ, et al.			
	4,835,003	5/30/89	BECKER			
	4,841,976	6/27/89	PACKARD, et al.			
	4,867,174	9/19/89	SKRIBISKI			
	4,884,579	12/5/89	ENGELSON			
	4,950,257	8/21/90	HIBBS, et al.			
	4,991,602	2/12/91	AMPLATZ, et			
	5,041,100	8/20/91	ROWLAND, et al.			
N	5,061,254	10/29/91	KARAKELLE, et al.			
<u> </u>	5,069,226	12/3/91	YAMAUCHI, et al.			
miner	Tom let			Date Consi	dered	

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

Approved for use through 10/31/2002, OMB 0851-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number. Substitute for form 1449A/PTO Complete if Known Application Number 10/647,119 **INFORMATION DISCLOSURE** Filing Date August 25, 2003 STATEMENT BY APPLICANT First Named Inventor Michael R. VIOLANTE et al. 3737 Group Art Unit (use as many sheets as necessary) **Examiner Name** Unassigned 2 of **Attorney Docket Number** 32286-192289 **U.S. PATENT DOCUMENTS Document Number** Date Examiner Name Sub-Filing Initial Class Class Date . 5,201,314 4/13/93 BOSLEY, et al. 5,331,027 7/19/94 WHITBOURNE 5,452,726 9/26/95 BURMEISTER, et al. 5,370,901 12/94 TOURNIER et al. 5,580,575 12/96 UNGER et al. 5,853,745 12/29/98 **DAROUICHE** 5,824,048 10/20/98 TUCH 5,120,770 06/09/1992 DOYLE et al. 08/22/2000 6,106,473 VIOLANTE et al. 3,605,750 09/1971 SHERIDAN et al. 4,111,190 09/1978 **PLUMRIDGE** 4,276,885 07/1981 TICKNER et al. 4,277,367 07/1981 MADSEN et al. 4,322,164 03/1982 SHAW et al. 4,386,612 06/1983 RODER et al. 4,490,139 12/1984 HUIZENGA et al: 4,567,896 02/1986 BARNEA et al. FOREIGN PATENT DOCUMENTS **Document Number** Date Name Sub-Trans-Class Class lation 04070965 A1 10/7/90 **EPO** 90/03768 4/19/90 **WIPO** OTHER (Including Author, Title, Date, Pertinent Pages, etc.) Current Problems in Diagnostic Radiology, Percutaneous Transluminal Angioplasty, Charles J. Tegtmeyer, Vol. XVI, No. 2, McGraw-Hill Encyclopedia of Science & Technology, 6th Edition, (1987) C.R. Martinson, et al.; Surface Coating, Vol. 18, p. Interpenetrating Polymer Networks, Daniel Klempner, (1978) Endovascular Surgery, Wesley S. Moore, M.D., et al. (1989 W.B. Saunders Company), pp. 157-159 Examiner **Date Considered** 3-22-06 EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

3

of

32286-192289

Approved for use through 10/31/2002. OMB 0651-0031*
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a vetid OMB control number.

Attomey Docket Number

Substitute for form 1449A/PTO Complete if Known Application Number 10/647,119 INFORMATION DISCLOSURE Filing Date August 25, 2003 STATEMENT BY APPLICANT First Named Inventor Michael R. VIOLANTE et al. Group Art Unit 3737 (use as many sheets as necessary) Examiner Name Unassigned

U.S. PATENT DOCUMENTS U.S. Patent Document Name of Patentee or Applicant Date of Publication of Pages, Columns, Lines, Where Relevant Examine Kind Code² of Cited Document Passages or Relevant Number MM-DD-YYYY Figures Appear (If known 4,572,203 **FEINSTEIN** 02/1986 4,582,061 FRY 04/1986 4,681,119 RASOR et al. 07/1987 4,697,595 BREYER et al. 11/1987 4,709,703 LAZAROW et al. 12/1987 4,718,433 **FEINSTEIN** 01/1988 4,718,907 KARWOSKI et al. 01/1988 4,805,628 FRY et al. 03/1989 4,869,259 **ELKINS** 09/1989 4,872,922 BUNKER et al. 10/1989 4,911,172 BUI et al. 03/1990 5,048,530 HURWITZ 09/1991 5,054,310 **FLYNN** 10/1991 5,095,911 POMERANZ 03/1992 5,213,569 **DAVIS** 05/1993 5,219,335 WILLARD et al. 06/1993 5,221,269 MILLER et al. 06/1993 5,221,269 BOSLEY 06/1993 5.333.613 TICKNER et al. 08/1994 5,344,494 DAVIDSON et al. 09/1994

				FOREIG	N PATENT DOCU	IMENTS		
Examiner	Cite	Fon	eign Patent Doo	ument	Name of Patentee	Date of Publication of	Pages, Columns, Lines, Where Relevant	
Initials*	No.1	Office ³	Number ^A	Kind Code ⁵ (if known)	or Applicant of Cited Document	Cited Document MM- DD-YYYY	Passages or Relevant Figures Appear	T ₆
M		WIPO	94/16739			08/1994		
M	r_	FR	2272633			12/1975		
The	¥(DE	3501355	A1		07/1985		-
111								
		ļ						
			L	4 1		1		

Examiner Signature	When	Date Considered	3-22-06	

SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.



EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. 2 See attached Kinds of U.S. Patent Documents. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the Indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 18 if possible. 6 Applicant is to place a check mark here if English language Translation is attached.

TANT & TA

of | 6

Approved for use through 10/31/2002, OMB 0651-0031

32286-192289

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Attorney Docket Number

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE
STATEMENT BY APPLICANT

Filing Date
First Named Inventor
Group Art Unit

Group Art Unit

Unassigned

Complete if Known

10/647,119

Filing Date
August 25, 2003

First Named Inventor
Michael R. VIOLANTE et al.

Group Art Unit
Unassigned

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of Cite T² Examiner the Item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue Initials No. number(s), publisher, city and/or country where published. Rompp Chemie Lexicon, Georg Thieme Verlag, Stuttgart, New York, 9. Auflage, 1992, Vol. 5 (Pi-S), pp. 4016 and 3575-3576. ("Schaumstoffe") Rompp Chemie Lexicon, Georg Thieme Verlag, Stuttgart, New York, 9. Auflage, 1992, Vol. 6 (T-Z), p. 4688. ("Treibmittel") M. R. VIOLANTE et al., "Particle Stabilized Bubbles For Enhanced Organ Ultrasound Imaging". Investigative Radiology, Vol. 26, Supp. I, November 1991, pp. S194-S197. Barbara A. CARROLL et al., "Gelatin Encapsulated Nitrogen Micro-Bibbles as Ultrasound Contrast Agents", Investigative Radiology, Vol. '15, May-June 1980, pp. 260-266. Jonathan OPHIR et al., "Contrast Agents for Diagnostic Ultrasound", Ultrasound Medicine and Biology, Vol. 15, No. 4, 1989, pp. 319-333. K.J. PARKER, et al., "A Particular Contrast Agent With Potential For UltraSound Imaging Of Liver," UltraSound in Med. & Biology, Vol. 13, No. 9, March 1987, pp. 555-568

			U.S. PATENT DOCUM	MENTS	
		U.S. Patent Document	Name of Patentee or Applicant	Date of Publication of	Pages, Columns, Lines, Where Relevant
Examiner Initials *	Cite No. ¹	Number Kind Code ² (if known)	of Cited Document	Cited Document MM-DD-YYYY	Passages or Relevant Figures Appear
V/Ms		5,383,466	PARTIKA	01/1995	
-0		5,409,688	QUAY	04/1995	
		5,454,373	KOGER et al.	10/1995	
		5,490,521	DAVIS et al.	02/1996	
		5,676,925	KLAVENESS et al.	10/1997	·
		5,690,908	DEUTSCH	11/1997	
V		5,120,770	DOYLE et al.	06/09/1992	
Ý					

Examiner Signature	Mila	Date Considered	3-22-06

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

VENABLE

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the Indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁶ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁸ Applicant is to place a check mark here if English language Translation Is attached.

> +

Approved for use through 10/31/2002, OMB 0651-0031 U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

of 6

Complete if Known				
Application Number	10/647,119			
Filing Date	August 25, 2003			
First Named Inventor	Michael R. VIOLANTE et al.			
Group Art Unit	3737			
Examiner Name	Unassigned			
Attorney Docket Number	32286-192289			

7		OTHER PRIOR ART NON PATENT LITERATURE DOCUMENTS	
Examiner Initials *	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
Au1		Diane BERGIN et al., "Echogenic Polymer Coating: Does It Improve Needle Visualization in Sonographically Guided Biopsy?", AJR: 178, May: 2002. pp. 1188-1190,	
7		Ronald H. GOTTLIEB, et al., "Coating Agent Permits Improved Visualization of Biopsy Needles During Sonography", AJR 171, November: 1998. pp. 1301-1302.	
		William C. CULP, et al., "Relative Ultrasonographic Echogenicity of Standard, Dimpled, and Polymeric-coated Needles", JVIR, Volume 11, March 2000, pp. 351-358.	
		Ronald H. GOTTLIEB et al., "ECHO-COAT™ Coating Agent Permits Improved Visualization of Biopsy Needles", Radiological Society of North America, Chicago, IL. December 2: 1997, pp. 1-8.	
		M. VIOLANTE et al., "Enhanced Ultrasound Visibility of Medical Devices", Society for Biomaterials, San Diego, CA. April 22-25, 1998.	
		M. R. VIOLANTE, "Improving Needle Ultrasound Visibility", Transactions of the Society for Biomaterials April 28-May 2: 1999.	
		Lisa A., CARDON et al., "Novel Polymer Coating Improves Needle Visualization", Abstract Presented at the American Heart Association 71st Scientific Session: 1998.	
		William C. CULP et al., "A New Echogenic Needle Coating to Aid Ultrasonographic Guidance", Abstract Presented at SCVIR 24th Annual Scientific Meeting: 1999.	
		W.R. LEES et al., "Trials Of A New Reflective Coating For Ultrasound Needles, Catheters And Guidewires", Abstract Presented at the 85th Scientific Assembly and Annual Meeting Radiological Society of North America: 1999.	
		John ZIMMERMAN et al., "Structural and Chemical Analysis of Coating Used to Enhance Ultrasonic Imaging", Presented at the Sixth World Biomaterials Congress, May: 2000.	
		STS Bio Polymers, Inc., Press Release, "ECHO-COAT® Ultrasound Coating Now Available On Guidewire Introducer And Co-Axial Introducer Needles", December 12, 2002.	
		STS Bio Polymers, Inc., Press Release, "Echo-Coat Ultrasound Coating Now Available On A Core Biopsy Needle", January 24, 2002.	
		STS Bio Polymers, Inc., Press Release, "STS Biopolymers Wins Gold Award for ECHO-COAT® Ultrasound Needles", June 25, 2001.	
		STS Bio Polymers, Inc., Press Release, "STS Biopolymers Wins Medical Design Excellence Award for ECHO-COAT® Ultrasound Needles", May 15, 2001.	-
		STS Blo Polymers, Inc., Press Release, "Enhanced Needle Visualization For Breast Localizations Under Ultrasound Guidance", May 15, 2001.	

Examiner Signature	Date Considered	3-22-06
--------------------	--------------------	---------

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.





¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ² Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the Indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

 \Box

Approved for use through 10/31/2002, OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

of

Complete if Known					
Application Number	10/647,119				
Filing Date	August 25, 2003				
First Named Inventor	Michael R. VIOLANTE et al.				
Group Art Unit	3737				
Examiner Name	Unassigned				
Attorney Docket Number	32286-192289				

·/		OTHER PRIOR ART NON PATENT LITERATURE DOCUMENTS	
Examiner Initials */	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
1/11		STS Bio Polymers, Inc., Press Release, "Echogenic Coatings Patent Granted to STS Biopolymers", September 13, 2000.	
		STS Bio Polymers, Inc., Press Release, "STS Biopolymers Launches ECHO-COAT™ Ultrasound Biopsy Needles" February 24, 2000.	
		STS Bio Polymers, Inc., Press Release, "STS Biopolymers Receive FDA 510(k) Clearance for ECHO-COAT™ Ultrasound Needles", March 17, 1999.	
		STS Bio Polymers, Inc., Press Release, "Novel Polymer Coating Improves Visibility of Devices in Ultrasound Images", November 16, 1998.	
		STS Bio Polymers, Inc., Press Release, "Advance in Ultrasound Imaging", February 24, 1998.	
V		STS Bio Polymers, Inc., Press Release, "Workshop L – Improving Needle Ultrasound Visibility", RSNA 1997.	
		0	

Examiner	11/1	Date		
Signature	Mh	Considered	3-22-06	



EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WiPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WiPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.